ET 09-161

CLASS Accreditation Services
An ANSI-ASQ National Accreditation Board Company

March 28, 2008

VIA EMAIL

Mr. Julius Knapp
Chief of the Office of Engineering & Technology
Federal Communication Commission
445 12th St. SW
Washington, DC 20554

RE: Letter of Request for FCC Recognition

Dear Mr. Knapp:

ACLASS Accreditation Services, An ANSI-ASQ National Accreditation Board Company, is an accreditation body in the United States providing laboratory accreditation to ISO/IEC 17025. ACLASS is requesting to be recognized by the FCC as an accreditation body for declaration of conformity for EMC laboratories as well as for the TCB programs under 47 CFR Parts 15 and 18.

ACLASS is a division within the American National Standards Institute (ANSI), which is currently recognized by the FCC and NIST under the NVCASE program to provide accreditation to telecommunication certification bodies. ACLASS is a signatory to several mutual recognition arrangements (MRA) including the worldwide International Laboratory Accreditation Cooperation (ILAC) MRA. In order to be a signatory to the ILAC MRA, ACLASS was required to undergo a thorough peer evaluation of our processes as well as our technical competency to ISO/IEC 17011. For your convenience I have enclosed copies of our mutual recognition arrangements showing ACLASS meets and was found in compliance with ISO/IEC 17011.

ACLASS possesses the necessary competence, technical assessors and commitment to conduct EMC accreditation activities. As an ANSI company, we are coordinated with other ANSI staff within the current FCC-NIST-ANSI collaboration as well as capable of providing services to laboratories in the specific FCC scopes. Because of our relationship with ANSI, we are able to share resources, including the sharing of technical assessors and other administrative resources. Moreover, ACLASS is currently in the process of being evaluated by NIST under its NVCASE program.

ACLASS is well recognized within industry and government for our accreditations to ISO/IEC 17025. For your convenience, I have enclosed examples of industry and government acceptance of ACLASS accreditations.

If you have any questions please do not hesitate to contact me directly at 703-351-9139 x203 or email at keith.greenaway@aclasscorp.com.

Warm Regards,

Keith Greenaway
Vice President

2009 N. 14th Street, Suite 502 | Arlington, VA 22201 | 703.351.9139 | www.aclasscorp.com

CLASS Accreditation Services

an ANSI-ASQ National Accreditation Board company

November 6, 2008

[redacted]

RE: Accreditation Assessment

Dear John:

Attached is a copy of your Accreditation Assessment Report. This report details the results of the ACLASS assessment of [redacted] on November 5-6, 2008.

The corrective action plan for the 2 major and 4 minor nonconformities must be submitted within 30 days to ACLASS. Based on the results of this assessment and submission of acceptable corrective actions, [redacted] is:

RECOMMENDED HOLD ACCREDITATION

Upon receipt of acceptable corrective action responses, our process requires the establishment of the Accreditation Review Panel. The purpose of the panel is to review your accreditation reports for technical compliance to the ACLASS requirements for ISO/IEC 17025. Please keep in mind that your corrective action responses are due within thirty days from the date of your recent assessment and the review panel process will not occur until your corrective action responses have been reviewed and accepted by the assessment team.

Thank you for choosing ACLASS as your accreditation body. We look forward to continuing our work with [redacted]

If you have any questions please contact ACLASS.

Sincerely,

Terry Burgess
ACLASS Assessor

ACLASS Accreditation Assessment Report

November 6, 2008

COMPANY:	[redacted]
LOCATION:	[redacted]
CONTACT:	[redacted]
PHONE:	[redacted]
FAX:	
EMAIL:	[redacted]
STANDARD:	ISO / IEC 17025:2005
DESCRIPTION OF SCOPE:	EMC Testing
DATE(S) OF ASSESSMENT:	November 5-6, 2008
DOCUMENTATION:	Management System Manual, Test Procedures
ASSESSOR(S):	Terry Burgess, Steve Berger (expert)
ATTACHMENTS:	A – Opening Meeting Checklist & Attendance Sheet(s) B – Confidentiality and Conflict of Interest Statement(s) C – Accreditation Assessment Schedule/Agenda D – Accreditation Checklists E – Non-Conformance Records F – Accreditation Recommendation Record G – Closing Meeting Record H – Final Draft Scope I – PT/ILC Summary Report Form 15
DISTRIBUTION:	Customer Representative / ACLASS Office

Summary of Accreditation Assessment Report

This report summarizes the results of the Accreditation Assessment of [redacted], [redacted] to ISO/IEC 17025 by ACLASS.

During the course of the assessment, the team noted the following:

- Review of proficiency testing/inter-laboratory comparison requirements showed evidence of participation as of the assessment visit.
- The internal audit program covers all requirements of ISO/IEC 17025.
- Staff technical qualifications; experience and authority were appropriate and evident.
- Adequacy of organization and procedures is appropriate to the size of the company.
- The laboratory's physical layout and accommodations were appropriate for the activities performed.
- All nonconformities identified during the assessment were reviewed and discussed with the management.

Considering this assessment is a sample, each of the nonconformities and observations should be reviewed in such a manner as to assure that they do not exist in other elements or other portions of your quality system. Nonconformities can be found in Attachment F.

There were 2 major, 3 minor nonconformities, and 4 opportunities. The company has 30 days to submit to ACLASS their corrective action plan for the nonconformities.

The next surveillance will be one year from the date of the accreditation decision or earlier as determined by ACLASS. Corrective actions will be verified at that time. Based on these findings the assessment team concluded to:

RECOMMENDED HOLD ACCREDITATION

As stated previously, all reports and records generated as a result of this assessment will remain confidential. They will not be shared with any other company.

Respectfully Submitted,

Terry Burgess

Attachment A – Opening Meeting Checklist & Attendance Sheet

ACLASS OPENING MEETING CHECK SHEET

Customer Name:	[redacted]
Lead Assessor/Presenter:	Terry Burgess
Date:	November 5, 2008

TOPICS REQUIRED TO BE ADDRESSED:	***Mark Box with "X" if Covered***
Introductions	☒ YES ☐ NO
Verify No Conflict of Interest • Confidentiality and Conflict of Interest Statements	☒ YES ☐ NO
Opening Meeting Attendance Sheet	☒ YES ☐ NO
Verify Scope and Requirements	☒ YES ☐ NO
Assessment Process Reviewed, which includes: • Sampling and Objective Evidence • Checklist • Non-conformance Record • Daily Meeting • Definitions of Findings • Accreditation Summary Sheet • Recommendation Definitions • Closing Meeting	☒ YES ☐ NO
Confirm Escort Names	☒ YES ☐ NO
Confirm Working and Meeting Room Provisions	☒ YES ☐ NO
Confirm Official Communication Links	☒ YES ☐ NO
Review Assessment Schedule, which includes: • Working Hours • Lunch Arrangements • Closing Meeting • Any Changes? o (If YES, note on copy of schedule and attach to this sheet)	☒ YES ☐ NO
Answer Any Questions	☒ YES ☐ NO

GENERAL COMMENTS: [redacted] laboratory will be visited first thing tomorrow morning. Assessment may be complete in two days.

ACLASS ATTENDANCE SHEET

Customer Name: [redacted]
City/State [redacted]

		Dates:	
Name	**Title/Affiliation**	**Opening**	**Closing**
Terry Burgess	ACLASS Assessor	X	X
Steve Berger	ACLASS Expert	X	X
[redacted]	[redacted]	X	X
George Tannahill	FCC Observer	X	
MaryJo DiBernardo	NIST Observer	X	X
Dan Hoolihan	NIST Observer	X	X

Attachment B – Confidentiality and Conflict of Interest Statement(s)

ACLASS CONFIDENTIAL INFORMATION AND NO CONFLICT OF INTEREST AGREEMENT

I am a designated Assessor and/or Expert and have executed an agreement with ACLASS to provide Accreditation Activities to ACLASS. As part of such Agreement, I am obligated to execute this Confidential Information and No Conflict of Interest Agreement ("Special Agreement") for each ACLASS customer for whom I perform Accreditation Activities.

I hereby execute this Special Agreement with respect to Washington Laboratories, Ltd. I confirm that I have not during the 24 month period prior to the date hereof directly or indirectly provided any consulting or other services which might reasonably be construed as a conflict of interest (e.g., any commercial, financial and other pressures) to or on behalf of Customer. I confirm that I will not during the 12 month period succeeding the last day on which I provide Accreditation Activities with respect to Customer pursuant to the Agreement or any future agreement between ACLASS and me, directly or indirectly provide any consulting or other services which might reasonably be construed as a conflict of interest to or on behalf (including, but not limited to Accreditation Activities for another accreditation body) to or on behalf of Customer.

I understand that in order to perform Accreditation Activities with respect to Customer, ACLASS and/or Customer shall provide me, (I) with materials concerning Customer and records of Customer which contain confidential information belonging to Customer, and (ii) with access to Customer's personnel who know confidential information belonging to Customer, which confidential information is not otherwise generally known by the public and which is called "Confidential Information" under this Special Agreement.

I shall keep Confidential Information secret and confidential, and not disclose such Confidential Information to any person or entity except for ACLASS. I shall deliver to ACLASS, or at ACLASS' direction, to Customer all materials and reports (including all copies) in my possession (including manuals, reports, computerized data contained in any form) upon receipt of a written letter from Customer or ACLASS instructing me to return such materials.

I understand that my obligations under this Special Agreement shall survive the termination of the Agreement.

Designated Assessor:	Terry Burgess
Date:	November 5, 2008

ACLASS CONFIDENTIAL INFORMATION AND NO CONFLICT OF INTEREST AGREEMENT

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I understand that my obligations under this Special Agreement shall survive the termination of the Agreement.

Designated Assessor:	Steve Berger
Date:	November 5, 2008

Attachment C – Accreditation Assessment Confirmation Letter

Accreditation Assessment Schedule

October 24, 2008

[redacted]

RE: Accreditation Assessment

Dear [redacted]

This letter is to confirm the dates scheduled for your ISO/IEC 17025 Accreditation Assessment. **The assessment will commence at 9 am on the morning of November 5, 2008 and will around noon on November 7.** We reserve the right to extend the audit should the assessor feel more time is necessary. Please see the attached schedule.

The assessment team will need a place to work from and would appreciate having a working lunch on the site to make best use of the time. The audit team will consist of the following:

Terry Burgess
Steve Berger

If you have any questions please do not hesitate to call.

Sincerely,

Terry Burgess
ACLASS Assessor

ACLASS Accreditation Assessment/Reassessment Schedule

[redacted]

ISO/IEC 17025:2005

Time/Date	Activity	Assessors
9am, Nov 5	Opening meeting	Terry
9:30 am	Laboratory tour	Terry/Steve
10 am	Begin ISO/IEC 17025 checklist section 4	Terry
	Witness tests	Steve
Noon	Lunch	
12:30 pm	Continue section 4	Terry
	Continue witnessing	Steve
4:45 pm	Progress meeting	Terry
8:30 am, Nov 6	Begin checklist section 5	Terry
	Continue witnessing	Steve
Noon	Lunch	
12:30 pm	Conclude section 5	Terry
	Continue witnessing	Steve
4:15 pm	Progress meeting	Terry
8:30 am Nov 7	Administrative tasks	Terry
	Conclude witnessing and EMC checklist	Steve
11 am	Closing meeting	Terry

Attachment D – Accreditation Checklists

Asterisks (*) indicate sections where objective evidence is required.

4. Organization/Management

4.1.1

Requirements	Document Review	Assessment Compliant
Is the laboratory/parent organization an entity that can be held legally responsible?		Limited Liability Corporation [redacted]-letter of incorporation

4.1.2

Requirements	Document Review	Assessment Compliant
Is the laboratory carrying out testing/calibration activities to meet the requirements of the International Standard and satisfying the needs of customers, regulatory authorities, or organizations providing recognition?		See below

4.1.3

Requirements	Document Review	Assessment Compliant
Does the laboratory's management system cover work carried out in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary/mobile facilities? Indicate which apply.		Laboratory facilities only covered by scope ([redacted] and [redacted] labs)

4.1.4

Requirements	Document Review	Assessment Compliant
If the laboratory is part of an organization performing activities other than testing or calibration, are the responsibilities of key personnel in the organization that have an involvement or influence on testing or calibration activities defined in order to identify potential conflicts of interest?		*Yes – organizational chart

NOTE: When the lab is part of a larger organization, organizational arrangements should be such that departments having conflicting interests (such as production, commercial marketing, or financing) do not adversely influence the lab's compliance with the requirements of the International Standard.

NOTE: If the lab desires to be recognized as a third-party lab, it should be able to demonstrate that it is impartial and that it and its personnel are free from any undue commercial, financial, and other pressures which might influence their technical judgment. The third-party testing or calibration lab should not engage in any activities that may endanger trust in its independence of judgment and integrity in relation to its testing or calibration activities.

4. Organization/Management (Continued)

4.1.5 Does the laboratory

Requirements	Document Review	Assessment Compliant
• have managerial and technical personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including the implementation, maintenance, and improvement of the management system, and to identify the occurrence of departures from the management system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures (see also 5.2)?		Management System Manual, paragraph 4.1.5.1
• have arrangements to ensure management/personnel are free from any undue internal/external commercial, financial/other pressures/influences that may adversely affect the quality of their work?		Management System Manual, paragraph 4.1.5.2
• have policies/procedures to ensure protection of customers' confidential information/proprietary rights, including procedures for protecting electronic storage/transmission of results?		*Non-Disclosure Agreement
• have policies/procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment, or operational integrity?		*Laboratory/ Employee Non-Disclosure Agreement
• define the organization/management structure of the laboratory, its place in any parent organization, and relationships among quality management, technical operations, and support services?		*Yes – organizational chart
• specify the responsibility, authority, and interrelationships of all personnel who manage, perform, or verify work affecting the quality of tests/calibrations?		*Org chart and job descriptions
• provide adequate supervision of testing/calibration staff, including trainees, by persons familiar with methods and procedures, the purpose of each test/calibration, and assessment of the test/calibration results?		One-on-one training
• have technical management which has overall responsibility for technical operations and the provision of the resources needed to ensure the required quality of laboratory operations?		[redacted] (org chart and job descriptions)

• have a member of staff who is appointed as quality manager (however named) who, irrespective of other duties/responsibilities, has the defined responsibility and authority for ensuring that the management system is implemented and followed at all times; does the quality manager have direct access to the highest level of management at which decisions are made on laboratory policy or resources?		[redacted] (org chart and job descriptions)
• have a member of staff who is appointed as technical manager who has overall responsibility for the technical operations? (Z-540)		N/A
• have deputies appointed for key managerial personnel (see note)?		* Management System Manual, paragraph 4.1.5.6 and job descriptions
• ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system?		All personnel required to read and sign MSM

NOTE: Individuals may have more than one function and it may be impractical to appoint deputies for every function.

4.1.6

Requirements	Document Review	Assessment Compliant
Does top management ensure that appropriate communication processes are established in the laboratory and that communication occurs regarding the effectiveness of the management system?		Yes – training program and weekly meetings

4.2 Management System

4.2.1

Requirements	Document Review	Assessment Compliant
Has the laboratory established, implemented, and maintained a management system appropriate to the scope of its activities?		Yes
Has the lab documented its policies, systems, programs, procedures, and instructions to the extent necessary to assure the quality of the test/calibration results?		Yes
Is the system's documentation communicated to, understood by, available to, and implemented by appropriate personnel?		Yes

4.2.2

Requirements	Document Review	Assessment Compliant
Are the laboratory's management system policies/objectives defined in a quality manual (however named), including a quality policy statement?		* Management System Manual
Are overall objectives established and reviewed during management review?		
Is the quality policy statement issued under the authority of top management? Does it include at least the following:		*In MSM signed by President
• laboratory management's commitment to good professional practice and to the quality of its testing/calibration in servicing its customers?		Management System Manual, paragraph 4.2.2
• management's statement of the laboratory's standard of service?		Management System Manual, paragraph 4.2.2
• Purpose of the management system related to quality?		Yes
• a requirement that all personnel concerned with testing/calibration activities within the laboratory familiarize themselves with the quality documentation and implement the policies/procedures in their work?		Yes
• laboratory management's commitment to comply with this International Standard and to continually improve the effectiveness of the management system?		Management System Manual, paragraph 4.2.2

NOTE: The quality policy statement should be concise and may include the requirement that tests/calibrations will always be carried out in accordance with stated methods and customers' requirements. When the test/calibration lab is part of a larger organization, some quality policy elements may be in other documents.

4.2.3

Requirements	Document Review	Assessment Compliant
Does evidence exist showing top management is committed to the development and implementation of the management system and to continually improve its effectiveness?		Yes – discussed with management

4.2.4

Requirements	Document Review	Assessment Compliant
Does top management communicate to the organization the importance of meeting customer requirements as well as statutory and regulatory requirements?		Yes – Regular meetings and MSM, read by all personnel, training records reviewed
Does the quality manual or related documentation contain a description of the organization and management structure of the laboratory, its place in any parent organization, and related organization charts? (Z-540)		*N/A
Does it also identify the laboratory's approved signatories (where this concept is appropriate)? (Z-540)		*N/A

4.2.5

Requirements	Document Review	Assessment Compliant
Does the quality manual include or make reference to supporting procedures including technical procedures?		* Management System Manual, paragraph 4.2.5
Does the quality manual outline the structure of documentation used in the management system?		* Management System Manual, paragraph 4.2.5 and 4.3.2

4.2.6

Requirements	Document Review	Assessment Compliant
Are the roles/responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with the International Standard, defined in the quality manual?		* Management System Manual, paragraph 4.2.6 and job descriptions

4.2.7

Requirements	Document Review	Assessment Compliant
Does top management ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented?		Yes – discussed with management

4.2 A.1 ACLASS Requirement - Field (On-Site) and Satellite Site Activities

Requirements	Document Review	Assessment Compliant
Does the quality manual cover field (on-site) operations, where applicable? Note: This only applies to laboratories that perform field (on-site) calibration or testing and laboratories with satellite sites.		*N/A

4.2 A.2 ACLASS Requirement - Field (On-Site) and Satellite Site Activities

Requirements	Document Review	Assessment Compliant
Has the laboratory identified the specific calibration(s) and/or test(s) conducted in the field (on-site) and/or at satellite sites? Note: This only applies to laboratories that perform field (on-site) calibration or testing and laboratories with satellite sites.		Safety and Environmental at the [redacted] site – to be identified in the scope footnotes

4.2 A.3 ACLASS Requirement - Satellite Site Activities

Requirements	Document Review	Assessment Compliant
Is the quality manual available to personnel at the satellite site(s) and does it include details of how the quality system is applied to satellite site(s)? These details shall include at a minimum: • Arrangements for supervision of the satellite site(s) where the site(s) is not controlled by the corporate organization • Organizational chart of the corporate organization showing lines of responsibility and authority of the satellite sites. Note: This only applies to laboratories with satellite sites.		*MSM 4.1.3

4.2 A.4 ACLASS Requirement - Field (On-Site) and Satellite Site Activities

Requirements	Document Review	Assessment Compliant
For organizations performing field (on-site) calibrations or maintaining satellite site(s), are the calibration and/or test reports/certificates issued from the corporate site ? Note: This only applies to laboratories that perform field (on-site) calibration or testing and laboratories with satellite sites.		Yes

4.3 Document Control

4.3.1 General

Requirements	Document Review	Assessment Compliant
Does the laboratory establish/maintain procedures to control all documents that form part of its management system (internally generated or from external sources), such as regulations, standards, other normative documents, test/calibration methods, as well as drawings, software, specifications, instructions, and manuals?		* Management System Manual, paragraph 4.3.1

NOTE: In this context "document" could be policy statements, procedures, specifications, calibration tables, charts, text books, posters, notices, memoranda, software, drawings, plans, etc. These may be on various media, whether hard copy or electronic, and they may be digital, analog, photographic, or written.

NOTE: The control of data related to testing/calibration is covered in 5.4.7. The control of records is covered in 4.13.

4.3.2 Document Approval/Issue

4.3.2.1

Requirements	Document Review	Assessment Compliant
Are all documents issued to personnel in the lab as part of the management system reviewed/approved for use by authorized personnel prior to issue?		TB-AA08-01
Is a master list/equivalent document control procedure identifying current revision status and distribution of documents in the management system established and readily available to preclude use of invalid/obsolete documents?		* TB-AA08-01

4.3.2.2 Do(es) the procedure(s) adopted ensure that:

Requirements	Document Review	Assessment Compliant
• authorized editions of appropriate documents are available at all locations where operations essential to effective functioning of the lab are performed?		TB-AA08-01
• documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements?		TB-AA08-01
• invalid/obsolete documents are promptly removed from all points of issue/use, or otherwise assured against unintended use?		Compliant – located in separate room
• obsolete documents retained for either legal or knowledge preservation purposes are suitably marked?		TB-AA08-01

4.3.2.3

Requirements	Document Review	Assessment Compliant
Are management system documents generated by the lab uniquely identified?		Yes
Does such identification include the date of issue/revision identification, page numbering, total number of pages or a mark to signify the end of the document, and issuing authority(ies)?		TB-AA08-02

4.3.3 Document Changes

4.3.3.1

Requirements	Document Review	Assessment Compliant
Are changes to documents reviewed and approved by the same function that performed the original review unless specifically designated otherwise?		TB-AA08-01
Do designated personnel have access to pertinent background information upon which to base their review and approval?		TB-AA08-01

4.3.3.2

Requirements	Document Review	Assessment Compliant
Is (where practicable) the altered or new text identified in the document or appropriate attachments?		TB-AA08-01

4.3.3.3

Requirements	Document Review	Assessment Compliant
If the lab's documentation control system allows for amendment of documents by hand pending re-issue of documents, are procedures and authorities for such amendments defined?		*MSM, 4.3.3
Are amendments clearly marked, initialed, and dated?		None seen
Is a revised document formally re-issued as soon as practicable?		TB-AA08-01

4.3.3.4

Requirements	Document Review	Assessment Compliant
Are procedures established to describe how changes in documents maintained in computerized systems are made and controlled?		*MSM, 4.3.3

4.4 Review of Requests/Tenders/Contracts

4.4.1

Requirements	Document Review	Assessment Compliant
Does the laboratory establish/maintain procedures for review of requests/tenders/contracts? Do the policies/procedures for these reviews leading to a contract for testing/calibration ensure that:		*MSM 4.4
• requirements, including methods to be used, are adequately defined, documented, and understood (see 5.4.2)?		Yes
• the laboratory has the capability/resources to meet requirements?		Yes
• the appropriate test/calibration method is selected and capable of meeting customers' requirements (see 5.4.2)?		Yes
Are any differences between the request or tender and contract resolved before any work commences? Is each contract acceptable to both the lab and customer?		Yes

NOTE: Request/tender/contract review should be conducted in a practical/efficient manner, and the effect of financial/legal/time schedule aspects should be taken into account. For internal customers, reviews of requests/tenders/contracts can be performed in a simplified way.

NOTE: Review of capability should establish that the lab possesses the necessary physical, personnel, and information resources, and that the lab's personnel have the skills and expertise necessary for the performance of tests/calibrations in question. The review may also encompass results of earlier participation in inter-laboratory comparisons or proficiency testing and/or running of trial test or calibration programs using samples or items of known value in order to determine uncertainties of measurements, limits of detection, confidence limits, etc.

NOTE: A contract may be any written/oral agreement to provide a customer with testing/calibration services.

4.4.2

Requirements	Document Review	Assessment Compliant
Are records of review, including any significant changes, maintained? Are records also maintained of pertinent discussions with a customer relating to the customer's requirements or results of the work during the period of execution of the contract?		*Yes – 10 years – MSM 4.13.2

NOTE: For review of routine and other simple tasks, the date and identification (e.g. the initials) of person in the lab responsible for carrying out contracted work are considered adequate. For repetitive routine tasks, the review need be made only at the initial enquiry stage or on granting of the contract for on-going routine work performed under a general agreement with the customer, provided the customer's requirements remain unchanged. For new, complex or advanced testing/calibration tasks, a more comprehensive record should be maintained.

4.4.3

Requirements	Document Review	Assessment Compliant
Does the review also cover any work that is subcontracted by the lab?		Yes – sampled contract reviews

4.4.4

Requirements	Document Review	Assessment Compliant
Is the customer informed of any deviation from the contract?		Yes

4.4.5

Requirements	Document Review	Assessment Compliant
If a contract needs to be amended after work has commenced, is the same contract review process repeated and are any amendments communicated to all affected personnel?		Yes

4.5 Subcontracting of Tests/Calibrations

4.5.1

Requirements	Document Review	Assessment Compliant
When a lab subcontracts work whether because of unforeseen reasons (e.g. workload, need for further expertise, or temporary incapacity) or on a continuing basis (e.g. through permanent subcontracting, agency or franchising arrangements), is work placed with a competent subcontractor? A competent subcontractor is one that, for example, complies with the International Standard for the work in question.		*Approved vendor's list

4.5.2

Requirements	Document Review	Assessment Compliant
Does the laboratory advise the customer of the arrangement in writing and, when appropriate, gain the approval of the customer (preferably in writing)?		*Yes – contract review

4.5.3

Requirements	Document Review	Assessment Compliant
Is the laboratory responsible to the customer for the subcontractor's work, except in the case where the customer/regulatory authority specifies which subcontractor is to be used?		Yes – reviewed sample test report for subcontracted tests

4.5.4

Requirements	Document Review	Assessment Compliant
Does the laboratory maintain a register of all subcontractors that it uses for tests/calibrations and a record of evidence of compliance with the International Standard for the work in question?		*Approved vendor's list

4.6 Purchasing Services/Supplies

4.6.1

Requirements	Document Review	Assessment Compliant
Does the laboratory have a policy/procedure for selection/purchasing of services/supplies it uses that affect the quality of tests/calibrations?		Management System Manual, paragraph 4.6
Do procedures exist for purchase, reception, and storage of reagents and lab consumable materials relevant for tests/calibrations?		Management System Manual, paragraph 4.6

4.6.2

Requirements	Document Review	Assessment Compliant
Does the laboratory ensure purchased supplies/reagents/consumable materials that affect the quality of tests/calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the method for test/calibrations concerned?		N/A
Do services/supplies used comply with specified requirements?		N/A
Are records of actions taken to check compliance maintained?		*N/A

4.6.3

Requirements	Document Review	Assessment Compliant
Do purchasing documents for items affecting the quality of laboratory output contain data describing services/supplies ordered?		*N/A
Are these purchasing documents reviewed/approved for technical content prior to release?		N/A